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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3736	11

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,937	WESTBROOK ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *9,13,17-19,22-24,27,30,34,35,40,45-47,51-61,65-68,71-77,79-81 and 84-87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1-4,6-8,10-12,14-16,20,21,25,26,28,29,31-33,36-39,41-44,48-50,62-64,69,70,78,82 and 83.

DETAILED ACTION

This is a final office action. Rejection referring to newly applied references US Patent No. 6,454,708 to Ferguson and US Patent No. 5,995,857 to Toomim et al. were necessitated by the applicants' amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6-8, 14-16, 31-33, 36, 39, 78, and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,454,708 to Ferguson et al. in view of US Patent No. 5,385,144 to Yaminishi et al. Ferguson describes a system comprising a physiological monitoring system 10, a means for removably affixing the monitoring system to the patient's body (col. 9, lines 17-21), sensors which may measure blood oxygenation and other vital signs (col. 8, lines 44-50), a storage memory 20 for storing signals from the sensors (col. 10, lines 1-11). The connection between the blood oxygen saturation data or other additional data may be transferred to the storage memory 20 wirelessly (col. 9, lines 61-66). The monitoring system further comprises a data transfer interface 39 that communicates signals from the sensors to an external computing device 30 (col. 1, line 60-col. 12, line 14). No lead wires exist between the patient and the storage memory. The system may also monitor whether events have occurred (col. 12, line 24-44) and be used to monitor sleep apnea and

other respiratory abnormalities (col. 6, lines 35-65). The system further includes a power source for providing electrical energy to circuitry 12 for operation (col. 8, lines 57-67). Ferguson is silent as to the details of the blood oxygenation sensor.

However, Yaminishi et al. discloses a pulse oximeter for determining a patient's blood oxygen saturation level. The oximeter comprises a reflectance-type sensor 1 (col. 2, lines 42-45) which contains a computing device 6 that determines pulse oxygen saturation or oxyhemoglobin desaturation level and pulse rate from the data signals of the sensor 1 (col. 2, line 65-col.3, line 5). Computing device 6 further identifies a respiratory event responsive to the data signals by detecting signals that indicate a threshold level of oxygen desaturation. The threshold level may be either a value set by a user (variable) or a fixed value (col. 3, lines 36-45). A power source 21 provides power to the system (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the pulse oximeter of Yaminishi et al. as the blood oxygenation sensor of Ferguson, since Ferguson discloses using a blood oxygenation sensor, and Yaminishi describes such a sensor.

As to the language "affixing . . .to the patient's forehead" on lines 4-5 of claim 1, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over Ferguson et al., as modified by Yaminishi et al., since the reference as modified discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647.

Claims 1-4, 6, 8, 20, 21, 25, 26, 28, 29, 36-38, 48-50, 69, 70, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,171,258

to Karakasoglu et al. in view of US Patent No. 5,995,857 to Toomim et al. and further in view of Yaminishi et al. Karakasoglu teaches a system comprising a physiological monitoring system 11, means 31 for removably affixing the system 11 to the patient's forehead (col. 2, lines 45-59), and a reflectance type pulse oximetry sensor S6 and circuitry which detect oxyhemoglobin saturation or SpO_2 levels and produces corresponding pulse oximetry data signals (col. 5, lines 24-45). The system further comprises storage memory 67 mounted on the physiological monitoring system 11 (col. 4, lines 47-51) and monitors sleep related obstructive respiratory events (apnea and hypopnea) of a patient from the sensor inputs (col. 6, lines 15-19). Karakasoglu teaches that the heart rate can be sensed by any one of a number of sensors provided, but fails to disclose the pulse oximetry sensor S6 as such a sensor.

However, Yaminishi teaches a pulse oximetry sensor 1 that detects and calculates a patient's arterial blood oxygen saturation level and pulse rate (col. 2, lines 66-69). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the pulse oximeter of Yaminishi et al. as the pulse oximetry sensor in the system of Karakasoglu since Karakasoglu teaches using a pulse oximetry sensor and Yaminishi describes such a sensor. The combination of Karakasoglu with Yaminishi discloses wires connecting the sensors and circuitry.

However, Toomim et al. discloses a physiological system in which electrical components may be connected either via wires or wirelessly (col. 4, lines 29-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use wireless means of communication in place of all wires in the system of

Karakasoglu et al., as modified by Yaminishi et al., since Toomim shows that wired and wireless means of communication are functionally equivalent.

With regard to claims 3, 20, 28, 37, and 50 Karakasoglu, as modified, teaches a patient head position and movement sensor S7 that produces a signal indicating the position and movement of the patient's head (col. 5, lines 28-33 of Karakasoglu).

With regard to claims 4, 20, 29, 38, and 50 the combination teaches a means 46 for producing a sound data signal indicating detected sounds produced by the patient (col. 3, lines13-24 of Karakasoglu).

With regard to claims 20, 21, 26, and 49 the combination describes a data transfer interface 111 communicating the sensor signals to the computing/expert system 106-108 that analyzes the signals, identifies abnormal respiratory events (apnea and hypopnea) and classifies the analyzed data signals into one or more type of events. The expert system 106-108 generates a sleep apnea risk evaluation report (RDI) as a summary of the identified respiratory events (col. 6, line 9-col. 7, line 25 of Karakasoglu).

With regard to claim 25, 48, and 69 the means 31 for removably affixing the system 11 to the patient's forehead is an adjustable strap (col. 2, lines 45-59 of Karakasoglu).

With regard to claims 36-38, 70, and 83, the combination further describes a power source 71 that provides electrical energy to the sensor and circuitry for operation (col. 4, lines 48-54 of Karakasoglu).

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson in view of Yaminishi, as applied to claims 1, 2, 6-8, 14-16, 31-33, 36, 39, 78, and 82 above, and further in view of US Patent No. 4,802,485 to Bowers et al. Ferguson, as modified, recites that additional data may be collected and provided to the monitoring system 10 (col. 9, lines 62-67 of Ferguson et al.) but fails to specify the system including a respiratory airflow detector. However, Bowers teaches a sleep apnea monitor 10 including a patient respiratory airflow detector 14 comprising a pressure transducer (col. 2, lines 37-40; col. 4, lines 40-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the sleep apnea monitor of Bowers et al. with the monitoring system of Ferguson in view of Yaminishi, since Ferguson, as modified, teaches that other sensors may be included in the monitoring system, and since Bowers teaches that the addition of a respiratory flow detector to a monitoring system would be useful in monitoring sleep apnea.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Yaminishi and Toomim, as applied to claims 1-4, 6, 8, 20, 21, 25, 26, 28, 29, 36-38, 48-50, 69, 70, 82, and 83 above, and further in view of US Patent No. 5, 329, 931 to Clauson. Karakasoglu, as modified, fails to teach a neuromuscular stimulation device. However, Clauson discloses the combination of blood gas saturation monitor 17 with a neuromuscular stimulator 26 (col. 2, lines 55-69; col. 4, lines 35-46). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to combine the monitor of Clauson with the monitoring system of Karakasoglu in view of Yaminishi and Toomim, in order to therapeutically stimulate a

patient to breathe more effectively when there is evidence that the patient's blood gas level is abnormal (col. 1, lines 25-39 of Clauson).

Claims 41, 43, 62, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Yaminishi and Toomim, as applied to claims 1-4, 6, 8, 20, 21, 25, 26, 28, 29, 36-38, 48-50, 69, 70, 82, and 83 above, and further in view of US Patent No. 6,135,952 to Coetzee. Karakasoglu, as modified, lacks applying a window median filter or other multiple data sample values averaging technique. However, Coetzee discloses a pulse oximetry device in which blood oxygenation signals undergo processing comprising a filter 334, where the first filter stage uses a window median filter that replaces a current data sample value with a median value selected form a predetermined number of data sample. The output of the median filter is subsequently filtered using another nonlinear predictor-corrector filter (fig. 3; col. 13, lines 5-29). Therefore, it would have been obvious to one of ordinary skill in the art to combine the pulse oximetry device of Coetzee with the system of Karakasoglu in view of Yaminishi and Toomim, in order to reduce noise from the pulse oximetry signals, thereby obtaining more accurate results.

Claims 41-43 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karakasoglu in view of Yaminishi and Toomim, as applied to claims 1-4, 6, 8, 20, 21, 25, 26, 28, 29, 36-38, 48-50, 69, 70, 82, and 83 above, and further in view of US Patent No. 6,035,223 to Baker, Jr. Karakasoglu, as modified, lacks applying a multiple data sample value averaging technique. However, Baker describes an oximetry system 100 in which filtered (step 208) and normalized (step 210) pulse

oximetry signals are averaged with a single-pole IIR filter to determine a metric 2. A determination of a metric 3 also involves using a whitening filter on the filtered and normalized pulse oximetry signals and then averaging the metric with a single-pole IIR filter with an appropriate time constant (figs. 1-3; col. 6, line 58-col. 7, line 48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the pulse oximetry system of Baker, Jr. with the system of Karakasoglu in view of Yaminishi and Toomim in order to verify proper application of the pulse oximetry sensor (col. 1, lines 27-35; col. 1, line 65-col. 2, line 25 of Baker, Jr.), thereby ensuring more accurate results and diagnosis of the patient.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson in view of Yaminishi et al. as applied to claims 1, 2, 6-8, 14-16, 31-33, 36, 39, 78, and 82 above, and further in view of US Patent No. 5,891,023 to Lynn. Ferguson, as modified teaches signaling an event based on thresholds (col. 12, lines 24-56 of Ferguson; col. 3, lines 34-65 of Yaminishi), but is silent as to how those thresholds are derived. However, Lynn teaches a sleep apnea diagnosing device in which a computing device that identifies SpO_2 data that indicates desaturation occurrences in accordance with the rate of change of SpO_2 desaturation data (col. 4, lines 16-31; figs. 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the rate of change of pulse oximetry data to identify desaturation of Ferguson in view of Yaminishi, since Ferguson, as modified, recites comparing oximetry information with thresholds to identify events, and Lynn discloses the rate of change of blood saturation may be used to identify such events.

Allowable Subject Matter

Claims 9, 13, 17-19, 22-24, 27, 30, 34, 35, 40, 45-47, 51-61, 65-68, 71-77, 79-81, 84-87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The indicated allowability of claims 9, 17-19, 22, 23, 27, 34, 35, 40, 45, 46, 52-61, 66, 67, 74-76 was discussed in a previous office action, paper No. 9, filed 10/6/03.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 13, the prior art of record fails to teach or fairly suggest a respiratory monitor comprising a transmission coil where the transmission coil uses a power source of the system.

With regard to claims 30 and 51, the prior art of record fails to teach or fairly suggest a risk evaluation system comprising the combination of an expert system that receives and analyzes pulse oximetry data signals from a pulse oximetry sensor and generates a sleep apnea risk evaluation report of the patient with a computing system that also receives and analyzes the pulse oximetry data signal and identifies any abnormal respiratory events of the patient, thereby producing at least one secondary respiratory event signal provided to the expert system.

With regard to claims 24, 47, 68, and 87, the prior art of record fails to teach or fairly suggest the combination of means for removably affixing a pulse oximetry sensor to a patient's forehead with a pulse oximetry sensor comprising an active pulse oximetry

sensor that applies positive pressure on the patient, where an active pulse oximetry sensor is described in the instant specification on p.28-29.

Regarding claim 65 the prior art of record fails to teach or fairly suggest a method of evaluating sleep apnea risk comprising the combination of attaching a physiological monitoring system to a patient's forehead, the system including a pulse oximetry sensor, providing the pulse oximetry data signals to an expert system that performs an analysis and generates a sleep apnea risk evaluation report, and identifying SpO_2 data that indicates desaturation occurrences in accordance with rate of change of SpO_2 desaturation data.

Regarding claims 71-77, the prior art of record fails to teach or fairly suggest a physiological monitoring system comprising the combination of a means for removably affixing a pulse oximetry sensor, patient head movement sensor, power means, and memory means to a patient's head with circuitry that receives pulse oximetry data signals and identifies a respiratory event of the patient, wherein the computing circuitry identifies said respiratory event in response to detecting pulse oximetry data signals that indicate a threshold level of oxyhemoglobin desaturation.

Regarding claims 79-81, the prior art of record fails to teach or fairly suggest a method of evaluating sleep apnea risk where the patient's oxyhemoglobin desaturation is compared with a variable threshold level of oxyhemoglobin desaturation to determine a respiratory event, where the threshold level is based on a known relationship between partial pressure of oxygen and oxyhemoglobin saturation, is at least one of peak or nadir oxyhemoglobin saturation or peak oxyhemoglobin resaturation, or is based at

least in part on an automated detection of changes in patient snoring sounds, head movement, and pulse rate.

Regarding claims 84-87, the prior art fails to teach or fairly suggest a means for removably affixing a physiological monitoring system to a patient's head, where the affixing means comprises the combination of an elastic strap with at least one foam pad mounted to the monitoring system and where the strap and foam pad cooperate to apply a pressure of a pulse oximetry sensor against a patient's forehead.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703)

605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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